

the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers.

32. (allowed) A sustained-release formulation for oral administration containing a cGMP PDE-5 inhibitor, which comprises a core containing the cGMP PDE-5 inhibitor and an outer coating impermeable to the cGMP PDE-5 inhibitor, the outer coating having an aperture for release of the cGMP PDE-5 inhibitor, provided that the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers.

33. (allowed) A controlled-release formulation for oral administration containing sildenafil, or a pharmaceutically acceptable salt thereof, provided that the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers.

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34. (allowed) A formulation as claimed in claim 33, wherein the cGMP PDE-5 inhibitor is sildenafil citrate.

35. (allowed) A sustained-release formulation for oral administration containing hydroxypropylmethyl cellulose and containing a cGMP PDE-5 inhibitor embedded in a matrix from which it is released by diffusion or erosion; provided that the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers.

36. (allowed) A sustained-release formulation for oral administration containing a buffering agent and a cGMP PDE-5 inhibitor embedded in a matrix from which it is released by diffusion or erosion, provided that the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers.

37. (allowed) A formulation as claimed in claim 35, wherein the hydroxypropylmethyl cellulose has a number average molecular weight in the range 80,000-250,000.

38. (allowed) A formulation as claimed in claim 35, wherein the hydroxypropylmethyl cellulose has a degree of methyl substitution in the range 19-30%.

39. (allowed) A formulation as claimed in claim 35, wherein the hydroxypropylmethyl cellulose has a degree of hydroxy substitution in the range 7-12%.

40. (allowed) A formulation as claimed in claim 35, wherein the hydroxypropylmethyl cellulose makes up 10-50% by weight of the formulation.

41. (allowed) A formulation as claimed in claim 31, wherein a multiplicity of coated cores is present.

42. (allowed) A formulation as claimed in claim 41, wherein the core further comprises a buffering agent.

43. (allowed) A formulation as claimed in claim 31, wherein the release rate-controlling membrane comprises an ammonio methacrylate copolymer and a plasticizer.

46. (allowed) A process for the production of a sustained-release formulation comprising a cGMP PDE-5 inhibitor embedded in a matrix from which it is released by diffusion or erosion, which comprises the steps of:

- (a) mixing the cGMP PDE-5 inhibitor with a matrix material, and pressing into tablets;
  - (b) forming a core comprising the cGMP PDE-5 inhibitor and then coating the core with a release rate-controlling membrane; or
  - (c) forming a core containing the cGMP PDE-5 inhibitor and then coating the
- 4/97, M4, (3/7)

core with a coating impermeable to the cGMP PDE-5 inhibitor;  
respectively.

47. (allowed) A method of treating sexual dysfunction, which comprises administering a sustained-release formulation, as defined in claim 31, to a mammal in need of such treatment.

48. (allowed) The method of claim 47, characterized in that, following administration, the mammal's sexual function is substantially improved for or after a sustained period of time.

49. (allowed) A method of improving sexual function in a mammal, which comprises administering a sustained-release formulation, as defined in claim 31, to the mammal.

50. (allowed) The method of claim 49, characterized in that, following administration, the mammal's sexual function is substantially improved for or after a sustained period of time.

El 51. (allowed) A method of increasing the probability of a nocturnal erection in a male mammal, which comprises administering a sustained-release formulation, as defined in claim 31, to the male mammal.

52. (allowed) A dual release formulation for oral administration having a first portion comprising a controlled-release formulation comprising a cGMP PDE-5 inhibitor and a second portion comprising a cGMP PDE-5 inhibitor in immediate release form.

53. (allowed) A product containing a controlled-release formulation comprising a cGMP PDE-5 inhibitor and a cGMP PDE-5 inhibitor in immediate release form, as a combined preparation for simultaneous, separate or sequential use in the treatment of sexual dysfunction.

54. (new) A formulation as claimed in claim 31, wherein the cGMP PDE-5  
4/97, M4, (4/7)

inhibitor is sildenafil or a pharmaceutically acceptable salt thereof.

55. (new) A formulation as claimed in claim 31, wherein the cGMP PDE-5 inhibitor is sildenafil citrate.

56. (new) A formulation as claimed in claim 32, wherein the cGMP PDE-5 inhibitor is sildenafil or a pharmaceutically acceptable salt thereof.

57. (new) A formulation as claimed in claim 32, wherein the cGMP PDE-5 inhibitor is sildenafil citrate.

58. (new) A formulation as claimed in claim 34, which is a sustained release formulation.

59. (new) A formulation as claimed in claim 52, wherein the cGMP PDE-5 inhibitor is sildenafil or a pharmaceutically acceptable salt thereof.

60. (new) A formulation as claimed in claim 52, wherein the cGMP PDE-5 inhibitor is sildenafil citrate.

61. (new) A product as claimed in claim 53, wherein the controlled release formulation comprises sildenafil or a pharmaceutically acceptable salt thereof and wherein the immediate release formulation comprises sildenafil or a pharmaceutically acceptable salt thereof.

62. (new) A product as claimed in claim 53, wherein the controlled release formulation comprises sildenafil citrate and wherein the immediate release formulation comprises sildenafil citrate.

63. (new) A dual release formulation for oral administration as claimed in claim 52, having a first portion comprising a sustained release formulation comprising sildenafil or a pharmaceutically acceptable salt thereof and a second portion comprising sildenafil or a pharmaceutically acceptable salt thereof in